CONFORMITY ASSESSMENT

2020EC4172UE

DATE OF RECEPTION
22/04/2020

APPLICANT

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IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCES
FILTERING HALF MASK referenced as Protective Mask SH-FP02/SH-FP03

TESTS CARRIED OUT

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ENAC is a signatory to the Multilateral Agreement (MLA), (MRA Mutual Recognition Agreement) of the European Cooperation for Accreditation (EA) and the International Laboratory Accreditation Cooperation (ILAC), in tesing.

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OBSERVATIONS

The PPE TYPE FILTERING HALF MASK referenced Protective Mask SH-FP02/SH-FP03, has been presented for the “EU” Type certification with compliance with Regulation (EU) 2016/425, according to harmonized standard EN 149:2001+A1:2009 “Respiratory protective devices. Filtering half masks to protect against particles.

This report and certification "EU" Type, is presented as an extension of the Certificate "EU" Type as No. 20/2567/00/0161 own brand manufacturer.

The manufacturer has presented the applicable Technical Documentation according to Annex II of the Regulation (EU) 2016/425.

For the certification, the manufacturer presents the following samples:

- Fifty (50) filtering half masks of PPE Protective Mask SH-FP02/SH-FP03.

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DESCRIPTION OF SAMPLES

FILTERING HALF MASK referenced Protective Mask SH-FP02/SH-FP03

The particle filtering half mask covers nose, mouth and chin.

The particle filtering half mask is composed by a principal body with 2 elastic straps to hold it, a nose clip, a nose cushion.

- The main body of the particle filtering half mask is made of different white layers.
- The head harness consists of two white elastic straps that allows the correct adjustment to the user ears. The straps are assembled in the body through four strap blocks in the lateral parts of the body.
- The nose clip is glued in the top of the outside part of the body of the particle filtering half mask.
- The nose cushion consists of a foam that has been heat sealed round the edge of the inner part of the body of the particle filtering half mask.

In this particle filtering half mask, air enters the mask through the different layers of the body and goes directly to the inner area of the main body of the particle filtering half mask. The exhaled air returns to the atmosphere through the same area of the main body of the mask.

The PPE is manufactured according to documentation presented by the customer for:

- Layers of the filter mask half:
    - Outer Veil: Polypropylene Spunbond Nonwoven Fabric
    - Large Particle Filter: Polyester Fibre Needle Punched Filter Media By Thermal bonding
    - Filter 1: Polypropylene Melt-Blown Filter Media (25g) with static electricity
    - Filter 2: Polypropylene Melt-Blown Filter Media (25g) with static electricity
    - Inner Veil: Polypropylene Spunbond Nonwoven Fabric
- Straps: Braided spandex bond.
- Nose clip: aluminium strip.
- Nose cushion: Polyurethane foam.

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ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

Annex II Regulation 2016/425	Clauses of Standard EN149:2001+A1:2009
1.1.1 Ergonomics	5; 7.7; 7.9
1.1.2.1. Optimum level of protection	5; 7.7; 7.9; 7.12
1.1.2.2. Classes of protection appropriate to different levels of risk	7.9
1.2.1. Absence of inherent risks and other nuisance factors.	7.6; 7.12; 7.14; 7.16
1.2.1.1. Suitable constituent materials	7.5; 7.6; 7.7; 7.10; 7.11
1.2.1.2. Satisfactory Surface condition of all PPE in contact with the user	7.7; 7.8
1.2.1.3. Maximum permissible user impediment.	7.7; 7.14
1.3.1 Adaptation of PPE to user morphology	7.7
1.3.2. Lightness and strength	7.4; 7.5; 7.7
1.4. Manufacturer's instructions and information	10
2.1. PPE incorporating adjustment systems.	7.13
2.3. PPE for the face, eyes and respiratory system.	7.14
2.4. PPE subject to ageing	7.6; 9; 10
2.6. PPE for use in potentially explosive atmospheres.	10
2.8. PPE for intervention in very dangerous situations.	10
2.9. PPE incorporating components wich can be adjusted or removed by the user.	7.13; 7.18
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety.	9
3.10.1. Respiratory protection.	7.6; 7.7; 7.8; 7.9; 7.12; 7.16; 7.17; 9; 10

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EVALUATION

The PPE TYPE FILTERING HALF MASK referenced as Protective Mask SH-FP02/SH-FP03, has been evaluated, according to Regulation (EU) 2016/425 and the technical specifications applicable to it, according to the harmonized standard EN 149:2001+A1:2009 “Respiratory protective devices. Filtering half masks to protect against particles " as FFP2 CLASS.

1.- TECHNICAL DOCUMENTATION AND MARKING

	RELATED DOCUMENT	ANNEX / CLAUSE	RESULTS
Technical documentation.	Regulation (UE) 2016/425	Annex III	Achieved
Marking	EN 149:2001+A1:2009	9.1, 9.2	Achieved
Manufacturer information *	Regulation (UE) 2016/425	Annex II point 1.4	Achieved
	EN 149:2001+A1:2009	10	Achieved

* It has been verified about the version in English presented by the client.

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EVALUATION

2.- REQUIREMENTS

2.1.- VISUAL INSPECTION

2.1.1- ACCORDING TO THE STANDARD EN 149:2001+A1:2009

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Packing	7.4	Filtering half mask shall be packaged to protect them from mechanical damage, thermal and contaminant conditions during storage.	Achieved	2020EC0141
Materials	7.5	The materials used shall withstand handling and use during the period for which the half-mask filter has been designed and shall not constitute a danger or damage to the user.	Achieved	2020EC0141
Materials	7.5	Any material in the filter that is released by the passage of the air flow through the filter shall not be a danger or damage to the user.	Achieved	2020EC0141
Finished of parts	7.8	Parts of the equipment that can be in contact with the user shall not have sharp edges or burrs.	Achieved	2020EC0141
Exhalation valve	7.15	If an exhalation valve is available, it shall be protected against dirt and mechanical damage and shall include any other device necessary to meet the requirements for leakage into the interior.	N.A.	---
Removable parts	7.18	All removable parts (if any) shall be easily connected and secured and, wherever possible, manually.	N.A.	---

N.A.: not applicable.

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EVALUATION

2.2.- TESTS

2.2.1- ACCORDING TO THE STANDARD EN 149:2001+A1:2009

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Practical behavior	7.6	The materials used shall withstand the cleaning and disinfecting agents and the procedures specified by the manufacturer.	Achieved	2020EC0141
	7.7	Check equipment imperfections that are not determined by other tests of this standard.	Achieved	2020EC0141
	7.10	Materials that may be in contact with the skin of the wearer shall not cause irritation or any other adverse health effects.	Achieved	2020EC0141
	7.13	The design of the head harness should be easy to put on and take off; And be adjustable or self-adjusting.	Achieved	2020EC0141
	7.14	The field of vision should be acceptable.	Achieved	2020EC0141
Total inward leakage	7.6	The materials used shall withstand the cleaning and disinfecting agents and the procedures specified by the manufacturer.	Achieved	2020EC0141
	7.9.1	At least 46/50 results of individual exercises for the total inward leakage shall not be greater than 25% for FFP1, 11% for FFP2 or 5% for FFP3.	FFP2 Achieved	2020EC0141
		At least 8/10 arithmetic means of the individual carriers for the total inward leakage shall not be greater than 22% for FFP1, 8% for FFP2 or 2% for FFP3.		2020EC0141
	7.10	Materials that may be in contact with the skin of the wearer shall not cause irritation or any other adverse health effects.	Achieved	2020EC0141
	7.13	The design of the head harness should be easy to put on and take off; And be adjustable or self-adjusting.	Achieved	2020EC0141

N.A.: not applicable.

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EVALUATION

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Penetration of filtering material	7.6	After cleaning and disinfection, the particle filtering half mask shall meet the penetration requirements of the relevant class.	Achieved	2020EC0141
	7.9.2	The penetration of the filtering half mask shall be 20% for FFP1, 6% for FFP2 and 1% for FFP3 when tested with sodium chloride or paraffin oil at 95 l / min.	FFP2 Achieved	2020EC0141
	7.17.3	After the obstruction treatment, the filtering half mask shall meet the penetration requirements of the filtering material.	N.A.	---
Inflammability	7.11	Materials shall not be flammable. The filtering half mask shall not continue burning more than 5 s after the flame has been removed.	Achieved	2020EC0141
CO_2 content of inhaled air.	7.12	The carbon dioxide content of the inhaled air should not exceed on average 1% (by volume).	Achieved	2020EC0141
Resistance to tensile of exhalation valves	7.15	When the exhalation valve is mounted on the face adapter, it shall withstand a tensile force of 10 N applied axially for 10 s.	N.A.	---
Resistance to breathing	7.15	Exhalation valves shall operate correctly in all directions.	N.A.	---
		The valves shall continue to operate after the continuous flow test.		
	7.16	The maximum resistance in inhalation at 30 l/min is for FFP1 0.6 mbar, for FFP2 0.7 mbar, for FFP3 1.0 mbar; in inhalation at 95 l/min is for FFP1 2.1 mbar, for FFP2 2.4 mbar, for FFP3 3.0 and in exhalation at 160 l/min is 3.0 mbar for FFP1, FFP2 and FFP3.	FFP2 Achieved	2020EC0141
	7.17.2	For filtering half masks with valves, after the clogging test, the breathing resistance shall not exceed 4 mbar for FFP1, 5 mbar for FFP2 and 7 mbar for FFP3 at a continuous flow rate of 95 l / min; the resistance to exhalation must not exceed 3 mbar at a continuous flow of 160 l / min.	N.A.	---
		For filtering half masks without valves, after the clogging test, the breathing resistance shall not exceed 3 mbar for FFP1, 4 mbar for FFP2 and 5 mbar for FFP3 at a continuous flow rate of 95 l / min.		---

N.A.: not applicable.

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EVALUATION

TEST	CLAUSE	REQUIREMENT	RESULT	REPORT No.
Clogging	7.17	The specified breathing resistance shall not be exceeded before a dust load of 833 mg·h/m^3 has been reached.	N.A.	---

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CONCLUSION OF THE CONFORMITY EVALUATION

Aitex, as Notified Body Nº 0161, concludes that:

The PPE TYPE FILTERING HALF MASK referenced as Protective Mask SH-FP02/SH-FP03, complies with the essential health and safety requirements in accordance with the provisions of Regulation (EU) 2016/425 according to harmonized standard EN 149:2001+A1:2009 “Respiratory protective devices. Filtering half masks to protect against particles ", as FFP2 CLASS.

The results of the tests carried out, as well as the evaluations, are valid only for the tested PPE.

The CAT. III PPE shall only be used in conjunction with one of the conformity assessment procedures according to Module C2 or Module D described in Article 19 letter c) of the Regulation (EU) 2016/425.

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Israel Soriano
Head of Advance Personal Protective Equipment Lab.

Digitally signed by PAULA LLACER GONZALBEZ - NIF:21688409F
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Reason: Autorizado
Location: Alcoy

LIABILITY CLAUSES

1.- AITEX is liable only for the results of the methods of analysis used, as expressed in the report and referring exclusively to the materials or samples indicated in the same which are in its possession, the professional and legal liability of the Centre being limited to these. Unless otherwise stated, the samples were freely chosen and sent by the applicant.
2.- AITEX shall not be liable in any case of misuse of the test materials nor for undue interpretation or use of this document
3.- The Offer and / or Order to which the applicant gives approval through signature and seal, constitutes the Legally Executable Agreement in which AITEX is responsible for safeguarding and guaranteeing the absolute confidentiality of the management of all the information obtained or created during the performance of the contracted activities.
4.- In the eventuality of discrepancies between reports, a check to settle the same will be carried out in the head offices of AITEX. Also, the applicants undertake to notify AITEX of any complaint received by them as a result of the report, exempting this Centre from all liability if such is not done, the periods of conservation of the samples being taken into account.
5.- AITEX is not responsible for the information provided by customers, which is reflected in the Report, and may affect the validity of the results.
6.- AITEX will provide at the request of the person concerned, the treatment of complaints procedure.
7.- AITEX is not responsible for an inadequate state of the sample received that could compromise the validity of the results, expressing such circumstance, in the test reports.
8.- AITEX may include in its reports, analyses, results, etc., any other evaluation which it considers necessary, even when it has not been specifically requested.
9.- When a Declaration of Conformity is requested, if not indicated otherwise, the decision rule will be applied according to ILAC-G8 & ISO 10576-1, in case of ambiguity, or indeterminacy
10.- The uncertainties of tests, which are made explicit in the Results Report, have been estimated for a k = 2 (95% probability of coverage). If not informed, they are available to the client in AITEX.
11. - The original materials and rests of samples, not subject to test, will be retained in AITEX during the twelve months following the issuance of the report, so that any check or claim which, in his case, wanted to make the applicant, should be exercised within the period indicated.
12.- This report may only be sent or delivered by hand to the applicant or to a person duly authorised by the same.
13.- The results of the tests and the statement of compliance with the specification in this report refer only to the test sample as it has been analyzed / tested and not the sample / item which has taken the test sample.
14.- The client must attend at all times, to the dates of the realization of the tests.
15.- According to Resolution EA (33) 31, the test reports must include the unique identification of the sample, and any brand or label of the manufacturer may be added. It is not allowed to re-issue test reports of untested sample names (references), they can only be re-issued for error correction or inclusion of omitted data that were already available at the time of the test. The laboratory can not assume responsibility for declaring that the product with the new trade name / trademark is strictly identical to the one originally tested; This responsibility belongs to the client.